

### REMARKS

The present Preliminary Amendment is responsive to the request for Removing the Finality of the Office Action pursuant to 37 C.F.R. § 1.129(a) mailed November 17, 2000 and further to the earlier preliminary amendment filed January 26, 2001. New claims 118-161 are added. Claims 88-104 and 106-161 are now pending in view of the above amendments. Support for the newly added claims can be found in Figures 14, 58, 89 and 90 and their corresponding descriptions. The HCV cDNA library in clone ATCC 40394 is disclosed on page 255 of the Specification. Disclosure related to antigen-antibody complex formations with epitopes of claimed polypeptides can be found in section IV.G. and throughout the Specification. Hybridization of oligonucleotides and stringency of hybridization protocols are disclosed in section II.H. on pages 61-63 and throughout the Specification. ELISA and radioimmunoassays using HCV polypeptides are disclosed in section IV.I. and throughout the Specification. Evidence distinguishing Hepatitis A and B virus polypeptides is disclosed in section IV.B.3. and throughout the Specification. Preparation, isolation and sequencing of the individual HCV cDNA clones and the composite sequences derived from them are disclosed in section IV.A of the Specification. Applications of the claimed methods in preparation of blood-related products and polyclonal antibodies, and in passive immunotherapy are disclosed on page 41, in sections II.B, G, and I and throughout the Specification.. No new matter is added. Entry and consideration of the above new claims are respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

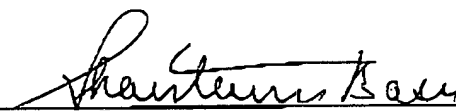
In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this

document to Deposit Account No. 03-1952 referencing docket no. 223002006313. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Claims:**

118. (New) A method of preparing biological samples from human individuals prior to use to prevent transmission of hepatitis C virus (HCV), said method comprising:

- (a) providing a supply of human biological samples; and
- (b) selecting from said supply HCV positive biological samples, wherein said HCV positive samples comprise either (i) a polynucleotide that hybridizes under stringent conditions to a polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof, or (ii) antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids encoded by a hepatitis C virus genome.

119. (New) A method of preparing biological samples from human individuals prior to use to prevent transmission of hepatitis C virus (HCV), said method comprising:

- (a) providing a supply of human biological samples; and
- (b) selecting from said supply HCV positive biological samples, wherein said HCV positive samples comprise either (i) a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in the lambda gt-11 cDNA library deposited as ATCC No. 40394 or (ii) antibodies that form an antigen-antibody complex with an HCV polypeptide sequence of at least 10 contiguous amino acid encoded by an HCV cDNA insert in the lambda gt-11 library deposited as ATCC deposit No. 40394.

120. (New) A method of preparing biological samples from human individuals comprising:

- (a) providing a supply of human biological samples; and

(b) selecting from said supply biological samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure 58.

121. (New) A method of preparing biological samples from human individuals comprising:

(a) providing a supply of human biological samples; and  
(b) selecting from said supply biological samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure 14.

122. (New) A method of preparing biological samples from human individuals comprising:

(a) providing a supply of human biological samples; and  
(b) selecting from said supply biological samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the hepatitis C virus (HCV) cDNA inserts in the lambda gt-11 cDNA library deposited as ATCC No. 40394.

123. (New) A method of preparing biological samples from human individuals comprising:

(a) providing a supply of human biological samples; and  
(b) selecting from said supply biological samples that comprise antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids found in Figure 90.

124. (New) A method of preparing biological samples from human individuals comprising:

(a) providing a supply of human biological samples; and

(b) selecting from said supply biological samples that comprise antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids found in Figure 14.

125. (New) A method of preparing biological samples from human individuals comprising:

- (a) providing a supply of human biological samples; and
- (b) selecting from said supply biological samples that comprise antibodies that form an antigen-antibody complex with a hepatitis C virus (HCV) polypeptide sequence of at least 10 contiguous amino acid encoded by an HCV cDNA insert in the lambda gt-11 library deposited as ATCC deposit No. 40394.

126. (New) A method according to any of claims 117-122 wherein said stringent conditions permit the formation of a stable hybrid duplex between said polynucleotide and said contiguous sequence and do not permit the formation of a stable duplex between said contiguous sequence and the genomes of Hepatitis B or Hepatitis A viruses.

127. (New) A method according to any of claims 117-122 wherein said polynucleotide is detectable in a PCR assay.

128. (New) A method according to claim 126 wherein said polynucleotide is detectable in a PCR assay.

129. (New) A method according to any of claims 118, 119, and 123-125 wherein said antibodies are detectable in an ELISA or radioimmunoassay.

130. (New) A method according to claim 129 wherein said ELISA or radioimmunoassay employs an antigen comprising said amino acid sequence made by recombinant expression.

131. (New) A method according to claim 130 wherein said antigen is a fusion protein.

132. (New) A method according to any of claims 117-125 wherein said biological samples are blood .

133. (New) A method according to claim 126 wherein said biological samples are blood.
134. (New) A method according to claim 127 wherein said biological samples are blood.
135. (New) A method according to claim 128 wherein said biological samples are blood.
136. (New) A method according to claim 129 wherein said biological samples are blood.
137. (New) A method according to claim 130 wherein said biological samples are blood.
138. (New) A method according to any of claims 117-125 wherein said biological samples are plasma.
139. (New) A method according to claim 126 wherein said biological samples are plasma.
140. (New) A method according to claim 127 wherein said biological samples are plasma.
141. (New) A method according to claim 128 wherein said biological samples are plasma.
142. (New) A method according to claim 129 wherein said biological samples are plasma.
143. (New) A method according to claim 130 wherein said biological samples are plasma.
144. (New) A method according to any of claims 117-125 wherein said biological samples are sera.
145. (New) A method according to claim 126 wherein said biological samples are sera.

146. (New) A method according to claim 127 wherein said biological samples are sera.
147. (New) A method according to claim 128 wherein said biological samples are sera.
148. (New) A method according to claim 129 wherein said biological samples are sera.
149. (New) A method according to claim 130 wherein said biological samples are sera.
150. (New) A method according to claim 132 further comprising employing biological samples that are not selected for a preparation of blood-related products.
151. (New) A method according to claim 133 further comprising employing biological samples that are not selected for a preparation of blood-related products.
152. (New) A method according to claim 138 further comprising employing biological samples that are not selected for a preparation of blood-related products.
153. (New) A method according to claim 139 further comprising employing biological samples that are not selected for a preparation of blood-related products.
154. (New) A method according to claim 132 further comprising employing said selected samples in passive immunotherapy.
155. (New) A method according to claim 133 further comprising employing said selected samples in passive immunotherapy.
156. (New) A method according to claim 138 further comprising employing said selected samples in passive immunotherapy.
157. (New) A method according to claim 142 further comprising employing said selected samples in passive immunotherapy.
158. (New) A method according to claim 132 further comprising employing said samples to prepare polyclonal antibodies.

159. (New) A method according to claim 133 further comprising employing said samples to prepare polyclonal antibodies.

160. (New) A method according to claim 138 further comprising employing said samples to prepare polyclonal antibodies.

161. (New) A method according to claim 142 further comprising employing said samples to prepare polyclonal antibodies.